

Notified Body n° 0426



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## **CERTIFICATE N° 062-02-06-DM**

*(in compliance with Annex II of the Directive 93/42/EEC)*

# **ITALCERT**

certifies that

Full Quality Assurance System  
applied for the design, manufacture and final inspection  
of "Medical Devices" - MD -

by the manufacturer

**MD S.r.l.**

Via Guido Rossa, 22/c - 30037 SCORZÈ (VE) - ITALY

in the headquarters located in

Via Guido Rossa, 22/c  
30037 SCORZÈ (VE) - ITALY

complies with the requirements stated in

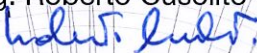
**Directive 93/42/EEC - Annex II (excluding point 4)**

and authorizes the same manufacturer to mark

**CE 0426**

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC  
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito

  
MANAGING DIRECTOR

First Issue date  
2006-05-24

Renewal date  
2014-05-24

Current Issue  
2018-09-27

Expire date  
2019-05-23

This certificate must be published only in integral form and accompanied by its Annex 1.  
This certificate is the English translation of the certificate n°062-02-06-DM issued by ITALCERT Srl in Italian language.  
In case of discrepancy you must refer to the original certificate issued in Italian language.



## Annex 1 to the Certificate n° 062-02-06-DM

- page 1 of 2 -

### Active medical device intended to administer and/or remove medicines, body liquids or other substances to or from the body

- Terminal units for medical gas and vacuum pipeline systems (class IIb)
 

PF-01xx-yyyy	Base blocks for terminal units for medical gas pipeline systems
PF-02xx-yyyy	Outlets for terminal units for medical gas pipeline systems
PF-06xx-yyyy	Probes for terminal units for medical gas pipeline systems
PF-36xx-yyyy	Doublers for terminal units for medical gas pipeline systems
KT-02xx-yyyy	Maintenance kits for terminal units
PF-34xx-yyyy	Pre-installed terminal units boxes
PF-66xx-yyyy	Hose assemblies
KT-01xx-yyyy	Maintenance kits for base blocks
  
- Second stage pressure regulators for medical gas pipeline systems (class IIb)
 

PF-05xx-yyyy / PF-37xx-yyyy	Line pressure regulators for medical gas pipeline systems
KT-0501-yyyy / KT-37xx-yyyy	Maintenance kits for line pressure regulators
PF-55xx-yyyy	High flow line pressure regulators
KT-55xx-yyyy	Maintenance kits for high flow line pressure regulators
PF-44xx-yyyy	Pre-assembled cabinets for second stage pressure regulation
  
- Terminal units for type 1 AGSS (Anaesthetic gas scavenging systems) (class IIa)
 

PF-02Ex-yyyy	Outlets for terminal units for AGSS
PF-01Ex-yyyy	Base blocks for terminal units for AGSS
PF-06Ex-yyyy	Probes for terminal units for AGSS
  
- Flow-meters for connection with terminal units of medical gas pipeline systems (class IIa)
 

PF-26xx-yyyy	Flow meters
PF-27xx-yyyy	Humidifiers for flow meters
  
- Medical suction devices
 

PF-38xx-yyyy	Vacuum regulators with collection for collection jar or hose barb fitting (class IIa)
PF-50xx-yyyy	Vacuum regulator – Probe – Flexible hose kit – Hose barb fitting/collection jar – filter (class IIb)
  
- Shut-off area valves and Vacuum control units (class IIb)
 

PF-03xx-yyyy	Shut-off area valves for medical gases and vacuum
PF-35xx-yyyy	Vacuum control units
PF-45xx-yyyy	Area valves pre-assembled cabinets
PF-46xx-yyyy	Shut off valves pre-assembled cabinets for fire control
PF-48xx-yyyy	Shut off line valves pre-assembled cabinets
PF-49xx-yyyy	Medical gas distribution system management cabinet
PF-61xx-yyyy	Shut-off area valves for medical gases and vacuum
PF-64xx-yyyy	AVSU (Area Valve Service Unit)
KT-61xx-yyyy	Maintenance kits for shut-off area valves

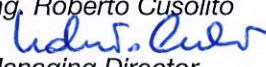
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## **Annex 1 to the Certificate n° 062-02-06-DM**

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- High pressure systems (class IIb)
  - PF-40xF-yyyy Pigtails for cylinders
  - PF-40xP-yyyy Pigtails for cylinder bundles
  - PF-40xT-yyyy High pressure flexible connections
  - PF-42xy-zzzz Cylinder manifolds
  
- First stage regulation devices (class IIb)
  - PF-43xx-yyyy First stage regulators for medical gas cylinder manifolds
  - KT-43xx-yyyy Maintenance kits for first stage pressure regulators
  - PF-51xx-yyyy Automatic change-over decompression units for medical gases
  - PF-52xx-yyyy Automatic change-over
  - PF-53xx-yyyy Emergency decompression units for medical gases
  - PF-62xx-yyyy First stage regulators for medical gas cylinder manifolds
  - KT-62xx-yyyy Maintenance kits for first stage pressure regulators
  - PF-70xx-yyyy High-flow manual change-over safety decompression station for medical gases
  
- Double-stage regulation devices (class IIb)
  - PF-54xx-yyyy Double-stage decompression units for medical gases
  - PF-56xx-yyyy Double-stage emergency decompression units for medical gases
  - PF-59xx-yyyy HTM 02-01 automatic manifolds for medical gases
  - PF-60xx-yyyy HTM 02-01 emergency reserve manifolds for medical gases

Milan, 2018-09-27

*dr. ing. Roberto Cusolito*  
  
Managing Director